EXHIBIT A

TENTATIVE DRAFT SETTLEMENT AGREEMENT, SUBJECT TO APPROVAL

This Settlement Agreement ("Agreement") is entered into by and among the United States of America on behalf of the United States Department of Health and Human Services ("HHS") and its Centers for Medicare & Medicaid Services ("CMS"), the NECC Tort Trustee on behalf of the NECC National Settlement Fund, the Insight Settlement Fund, the Inspira Settlement Fund, and the High Point Settlement Fund, and the MPS Class Counsel and the MPS Settlement Fund Administrator on behalf of the MPS Settlement Fund. All terms not otherwise defined in the body of this Agreement shall have the meanings set forth in Attachment A.

WHEREAS, CMS has asserted Medicare Secondary Payer ("MSP") claims pursuant to 42 U.S.C. § 1395y(b) against the Five NECC Settlement Funds with respect to Parts A and B Medicare-covered items and services associated with injuries from the administration of NECC products paid and to be paid under Medicare on behalf of Medicare-Entitled Claimants;

WHEREAS, the NECC Tort Trustee and MPS Class Counsel dispute the amount of CMS's MSP claims, and through good faith negotiations, the parties have reached an agreement to resolve this dispute, and their agreement is set forth below;

WHEREAS, Participating Lienholders and certain Non-Participating Lienholders have asserted medical liens against certain Claimants' payments from the Five NECC Settlement Funds as a result of payments made on behalf of GHP-Entitled Claimants for covered items and services associated with injuries from the administration of NECC products;

WHEREAS, the NECC Tort Trustee and MPS Class Counsel believe that it is in the best interests of many GHP-Entitled Claimants to resolve the medical liens asserted by Participating Lienholders so that payments may be made to GHP-Entitled Claimants from the Five Settlement Funds.

WHEREAS, Claimants to the Five NECC Settlement Funds have filed their claims under one of Seven Claims Categories, the values of which have been set according to various factors. For the NECC National Settlement, the National Settlement Administrator determines which claims fall into Injury Categories I, II, III, IV, V, VI, or VII. (See Attachment C for a listing of categories and the injuries included in each category.)

WHEREAS, the settlement administrator for each of the Insight Settlement, Inspira Settlement and High Point Settlement determines which claims fall into Injury Categories I, II, III, IV, V, VI or VII for the Insight Settlement, Inspira Settlement, and High Point Settlement;

WHEREAS the MPS Settlement Fund Administrator relies upon the National Settlement Administrator's determinations of which claims fall into Injury Categories I, II, III, IV, V, VI, or VII for the MPS Settlement;

WHEREAS, the NECC Tort Trustee is responsible for making payments to Claimants from the NECC National Settlement Fund, the Insight Settlement Fund, the Inspira Settlement Fund, and the High Point Settlement Fund;

WHEREAS, the MPS Settlement Fund Administrator is responsible for making payments to Claimants from the MPS Settlement Fund, pursuant to the terms of the MPS Settlement and Order authorizing distributions to be obtained from the Circuit Court overseeing the Settlement.

NOW THEREFORE, in consideration of the mutual covenants contained herein, the parties agree as follows:

I. Payments from the Five NECC Settlements to Categories I through VI Claimants

A. Medicare-Entitled Only Claimants with No Primary Lien from a Medical Lienholder: Any Medicare-Entitled Claimant for whom the NECC Tort Trustee or the MPS Settlement Fund Administrator has not received notice of the assertion of a Primary Lien by any other Medical Lienholder, shall have deducted from each Settlement Payment made to that Claimant, the Negotiated Lien Payment Amount, as determined by applying the relevant percentage contained in Attachment B (the "Negotiated Lien Payment Amount"). The Negotiated Lien Payment Amount deducted from the Claimant's Settlement Payments shall be held in reserve by the NECC Tort Trustee and/or the MPS Settlement Fund Administrator and paid to CMS.

CMS shall not receive any payment relating to payments by the Five NECC Settlements on behalf of any Claimant who became Medicare-eligible post May 31, 2013.

- B. <u>GHP-Entitled Only Claimants with No Primary Lien from Medicare or Another Medical Lienholder</u>: Any GHP-Entitled Claimant who is not a Medicare-Entitled Claimant and for whom the NECC Tort Trustee or the MPS Settlement Administrator has notice of only a Primary Lien by a Participating Lienholder shall have the Negotiated Lien Payment Amount deducted from all Settlement Payments made to that Claimant. That amount shall be held in reserve by the NECC Tort Trustee and/or the MPS Settlement Fund Administrator and paid to the appropriate Participating Lienholder.
- C. Medicare-Entitled Claimants Who Are Also GHP-Entitled Claimants With A Primary Lien From A Participating Lienholder: Any Medicare-Entitled Claimant, for whom the NECC Tort Trustee or the MPS Settlement Fund Administrator also has notice of the assertion of a Primary Lien by a Participating Lienholder shall have the Negotiated Lien Payment Amount deducted from all Settlement Payments made to that Claimant. That amount(s) shall be held in reserve by the NECC Tort Trustee and/or the MPS Settlement Fund Administrator and paid 50% to CMS and 50% to the appropriate Participating Lienholder upon the receipt by the Tort Trustee and/or the MPS Settlement Fund Administrator of proof of GHP coverage. The Tort Trustee and/or the MPS Settlement Fund Administrator shall provide to CMS proof of GHP coverage. If the Tort Trustee and/or the MPS Settlement Fund Administrator do not provide proof of GHP coverage to CMS, Medicare shall receive 100% of the Negotiated Lien Payment Amount. Proof of GHP coverage may consist of a spreadsheet indicating coverage by a GHP or other evidence of coverage provided to the Tort Trustee by the GHP, the Claimant, or both.
- Medicare-Entitled Claimants With Primary Liens from Non-D. Participating Lienholders: Any Medicare-Entitled Claimant, for whom the NECC Tort Trustee or the MPS Settlement Fund Administrator also has notice of the assertion of a Primary Lien by a Non-Participating Lienholder, shall have 50% of the Negotiated Lien Payment Amount deducted from all Settlement Payments made to that Claimant and that amount(s) shall be held in reserve by the NECC Tort Trustee and/or the MPS Settlement Fund Administrator and paid to CMS. Proof of coverage by the Primary Non-Participating Lienholder(s) shall be provided by the Tort Trustee or the MPS Settlement Fund Administrator to CMS. If the Tort Trustee and/or the MPS Settlement Fund Administrator do not provide proof of primary coverage to CMS, Medicare shall receive 100% of the Negotiated Lien Payment Amount. The Claimant will be responsible for resolving the Non-Participating Lienholder's lien and providing proof of that resolution to the Tort Trustee and/or the MPS Settlement Fund Administrator before any payment may be made to the Claimant from any of the Five Settlement Funds. Proof of coverage by a Non-Participating Lienholder to be provided to CMS

may consist of a copy of the lien asserted by the Non-Participating Lienholder provided to the Tort Trustee or the MPS Settlement Fund Administrator.

E. If the terms of any other agreement(s) entered into by a GHP (as defined in this Agreement) allow that GHP to opt out of the Negotiated Lien Payment terms in paragraph I.C. above, Medicare's payment under this Agreement shall be governed by paragraph I.D.

II. Payments from the Five NECC Settlements to Category VII Claimants

CMS agrees not to pursue any MSP claims for Parts A and B Medicare-covered items and services relating to payments made to any Category VII Claimant from the Five NECC Settlements.

III. Reporting Requirements Under 42 USC § 1395 y(b)(8)

With respect to reporting requirements of Section III of the Medicare, Medicaid & SCHIP Extension Act of 2007, as set forth in 42 USC §1395y(b)(8) and the program instructions established thereunder, the United States agrees that, except for any reporting requirements set forth in this Agreement, any Responsible Reporting Entity, as defined by CMS program instructions, is not required to report with respect to payments made by the Five NECC Settlement Funds paid to Claimants.

IV. Opt-Out Medicare-Entitled Claimants and Opt-Out GHP-Entitled Claimants

Any Medicare-Entitled Claimant or GHP-Entitled Claimant, whose claim 1) has been determined by the NECC Tort Trustee to fall into Injury Categories I, II, III, IV, or V in the National Settlement; 2) has been determined to have a claim asserted by Medicare or a GHP against their Settlement Payments; or 3) has been determined by the Insight Settlement Administrator to fall into Category I, II, III, IV, V or VI in the Insight Settlement, may elect to opt out of this Settlement Agreement. To be effective, a Notice of Lien Opt-Out, completed and signed by the Claimant, must be mailed and postmarked no later than 30 days after being given notice by the NECC Tort Trustee of the Claimant's entitlement to opt-out ("a Timely Notice of Lien Opt-Out"). By electing to opt-out, the Claimant agrees to negotiate individually with CMS and/or the GHP to resolve CMS' and/or the GHP's claim(s). Such notice may be given by the Claimant immediately after execution of this Agreement without regard to any delay for court approval or otherwise. Once a Claimant submits a Timely Notice of Lien Opt-Out to

the NECC Tort Trustee, the Negotiated Lien Payment Amount as reflected in Attachment B, and any other term of this Agreement, shall not apply with respect to any payments made by the Five Settlement Funds to the Opt-Out Medicare-Entitled or Opt-Out GHP-Entitled Claimant and shall not bind CMS, the GHP, the Claimant or the Claimant's attorney, in any individual negotiation or resolution of the amount owed CMS or the GHP by the Claimant.

The Tort Trustee and the MPS Settlement Fund Administrator shall withhold all distributions to Medicare-Entitled Claimants and GHP-Entitled Claimants who timely submit a Timely Notice of Lien Opt-Out until CMS and/or the appropriate Participating Lienholder who has asserted a lien against a GHP-Entitled Claimant provides the Tort Trustee and/or the MPS Settlement Fund Administrator with written confirmation that the Claimant's Medicare claim and/or GHP lien is resolved, including what portion, if any, of the Settlement Payment(s) to the Claimant shall be remitted to CMS and/or the Participating Lienholder.

Α. Opt-Out Medicare-Entitled Claimants: Pursuant to Section IV.C. of this agreement, the NECC Tort Trustee shall provide Opt-Out Medicare-Entitled Claimant data to CMS in order to initiate recovery cases with the Benefit Coordination & Recovery Center ("BCRC"). The Tort Trustee will also provide electronic copies of each Opt-Out Medicare Entitled Claimant's opt out letter, which will include attorney contact information and the Medicare Entitled Claimant's signature. This document will serve as proof of representation to permit the BCRC to issue copies of correspondence to the attorney identified by the Medicare-Entitled Claimant. To the extent that Medicare-Entitled Claimants who submit a Timely Notice of Lien Opt-Out have not been contacted by BCRC to address CMS recovery claims within 30 calendar days of the NECC Tort Trustee providing to CMS the requisite data points set forth above, a Claimant who has opted-out (or his/her attorney) may contact the Tort Trustee who, in turn, will communicate with CMS to resolve the issue. (The Tort Trustee may designate to Medicare-Entitled Claimants an agent to carry out these duties). Once the recovery case is initiated by BCRC, attorneys may continue to work directly with BCRC to resolve an Opt-Out Medicare-Entitled Claimant's recovery claim. The process will include obtaining a Conditional Payment Notice ("CPN"), providing BCRC with final settlement details, and obtaining a recovery demand letter from CMS. In the event that CMS receives payment for an Opt-Out Medicare Claimant's recovery claim and must subsequently issue a refund, CMS will issue such refund to the Opt-Out Medicare Entitled Claimant as the payee, regardless of whether the NECC Tort Trustee was the payor. Opt-Out Medicare-Entitled Claimants shall present the recovery demand letter to the Tort Trustee and/or the MPS Settlement Fund Administrator before any Settlement Payments are made to the Claimant from the Five

Settlement Funds. The amounts indicated on the recovery demand letter shall be withheld from all Settlement Payment(s) to the Claimant for payment to CMS. If there have been no other medical liens asserted by a Medical Lienholder, once the amounts indicated on the recovery demand letter have been retained and/or paid to CMS, the remainder of any payments due to the Claimant may be distributed to the Claimant and/or his or her agents or attorneys.

- B. <u>Court Approval and NECC Tort Trustee Notice of Right to Opt-Out:</u> This Agreement shall become effective upon its execution by all of the parties to it and its approval by the MDL Court and, for purposes only of MPS settling parties, the MPS Court. Within thirty days of such approval, the Tort Trustee shall notify Claimants who are entitled to opt-out and whose claims have been finally approved for payments from the Five NECC Settlement Funds that they have the right to file a Notice of Opt Out.
- C. <u>Medicare Opt-Out Status Reporting</u>: On a weekly basis in 2016 and on a monthly basis thereafter, the Tort Trustee shall then provide a report (the "Medicare Opt-Out Status Report(s)") to counsel for the United States and the MPS Settlement Fund Administrator that includes the following information for each known Opt-Out Medicare-Entitled Claimant to date: first and last names, date of birth, gender, social security number, Medicare health insurance claim number (if known), address, claim category, amount(s) awarded to date from the National Settlement, date of correspondence offering opt-out (if applicable), date when the opt-out was postmarked, and the name and address of the attorney representing each Medicare-Entitled Claimant (if represented).

V. Releases

A. As payments are made to individual Claimants, the United States releases the NECC Tort Trustee, the MPS Settlement Fund Administrator, MPS Class Counsel, MPS Defendants, NECC, the Other Settling Defendants, and the Medicare-Entitled Claimants who do not file a Timely Notice of Lien Opt Out and upon whose behalf a payment(s) has been made to the United States, as well as their attorneys, agents, executors and administrators, from any and all claims which the United States now has or which may hereafter accrue under the MSP Statute, 42 U.S.C. § 1395y(b) to recover conditional payments made on behalf of the Medicare-Entitled Claimants who did not file a Timely Notice of Lien Opt Out that relate to payments by the Five NECC Settlement Funds or any other settlement payments for injuries associated with NECC products arising from a settlement entered into as of March 25, 2016.

Notwithstanding any other provision of this agreement, the United States specifically does not release:

- 1. Any claim arising under criminal law;
- 2. Any criminal, civil, or administrative claims, rights, or defenses arising under Title 26, United States Code (Internal Revenue Code);
- 3. Any claims, rights or defenses arising under 31 U.S.C. §§ 3729 et seq. (False Claims Act); 31 U.S.C. § 3801, et seq. (Program Frauds Civil Remedies Act); 42 U.S.C. §§ 1320a-7a (Civil Monetary Penalties Statute), or any common law cause of action for fraud;
- 4. Any contribution or indemnity claims against entities or individuals other than the parties released by this Settlement Agreement;
 - 5. Any obligations created by this Settlement Agreement; and
- 6. Any claims, rights or defenses not specifically released or relinquished in this Settlement Agreement.

VI. Agreement with Participating Lienholders

The NECC Tort Trustee and the MPS Settlement Fund Administrator hereby represent that they have entered or will enter into agreements with the Participating Lienholders to resolve their medical liens on terms substantially identical to the terms in this agreement. Copies of those agreements have been or will be provided to CMS.

VII. Electronic Payments and Reports

Payments due shall be made by electronic funds transfer pursuant to instructions provided to the NECC Tort Trustee and the MPS Settlement Fund Administrator by counsel for the United States, within 30 days of the end of the month in which payments accrued. On a quarterly basis, the NECC Tort Trustee and/or the MPS Settlement Fund Administrator shall submit a Post-Payment Report (attached hereto as Attachment D) to counsel for the United States and Medicare (CMS) providing CMS-requested information regarding payments and claimants on whose behalf the NECC Tort Trustee and/or the MPS Settlement Fund Administrator has remitted funds to the United States during that calendar quarter. The NECC Tort

Case 1:13-md-02419-RWZ Document 3068-1 Filed 08/23/16 Page 9 of 13

FOR SETTLEMENT PURPOSES ONLY; CONFIDENTIAL

Trustee and the MPS Settlement Fund Administrator will use best efforts to include on the Post-Payment Report each Settling Medicare-Entitled Claimant's Medicare health insurance claim number (the number on the Medicare card). Identifying information regarding Settling Medicare-Entitled Claimants will be protected as confidential to the extent provided by federal law. Unless instructed otherwise by counsel for the United States, all reports should be provided to Cathy Burdette at the United States Department of Justice and ______ at CMS as an attachment to email with the heading "NECC Settlement Payments."

VIII. Determining Which Claimants Are Medicare-Entitled Claimants

The parties understand and agree that payments to Claimants by the NECC Tort Trustee and the MPS Settlement Fund Administrator shall be made on a rolling basis, as claims are approved and paid. The NECC Tort Trustee and the MPS Settlement Fund Administrator shall provide CMS' designated contact person with a completed spreadsheet of Claimants for each Claimant approved for payment in a particular batch, as specified on Attachment E, to receive payments before each distribution and further shall withhold payments for five days after processing each such spreadsheet so that CMS can approve the reconciliation spreadsheet (form attached at Attachment E) of the Medicare status of Claimants to receive payments. A reconciliation spreadsheet template shall be provided by CMS to the NECC Tort Trustee who shall provide a copy to the MPS Settlement Fund Administrator for its use.

Each Medicare-Entitled Claimant will be notified by the NECC Tort Trustee in the letter attached as A-1 of his or her one time opportunity to settle Medicare's claim. Each Settling Medicare-Entitled Claimant shall, by executing the applicable portion of Exhibit A-1 specifically: (i) provide his or her Medicare health insurance claim number (the number on the Medicare card); (ii) waive the right to receive a formal demand for recovery of Medicare conditional payments related to his or her receipt of Settlement Payments from the Five NECC Settlement Funds; (iii) waive the right to request a waiver of recovery pursuant to § 1870(c) of the Social Security Act (42 U.S.C. § 1395gg(c)) of the United States' claim for reimbursement of Medicare conditional payments related to his or her receipt of Settlement Payments; and (iv) waive any administrative or judicial appeal rights he or she may have with respect to the United States' claim for reimbursement of Medicare.

IX. <u>Disputes</u>

If any dispute arises between the parties concerning this Agreement, the parties agree to attempt to resolve such dispute in good faith.

X. Notices

- a. Notice to CMS shall be provided to:
- b. Notice to the NECC Tort Trustee shall be provided to:
- c. Notice to the MPS Settlement Fund Administrator shall be provided to:

DEFINITIONS

- 1. **Bankruptcy Court** means the United States Bankruptcy Court for the District of Massachusetts, Eastern Division.
- 2. **Claimant(s)** means any person or estate entitled to be paid funds from one of the Five NECC settlements.
- 3. **Five NECC Settlement Funds** means the funds available for distribution to Claimants from the NECC National Settlement, the Insight Settlement, the Inspira Settlement, the High Point Settlement, and the MPS Settlement.
- 4. GHP means a Group Health Plan, Part C Medicare Advantage plan, workers compensation insurance or other primary insurance at any time between September 1, 2012 and May 31, 2013, and such insurance has reason to believe it paid medical bills resulting from personal injuries arising from the administration of NECC products and such belief is not disputed by the Claimant.
- 5. **GHP-Entitled Claimant(s)** means a Claimant who was covered by a GHP, as defined above. GHP-Entitled Claimant(s) does not include a Claimant who was covered by Medicaid or a Medi-Gap Plan or a Part D Plan which is not waived by a Participating Lienholder.
- 6. **High Point Settlement Fund** means the fund established pursuant to the High Point Settlement Agreement approved by the Bankruptcy Court.
- 7. **Inspira Settlement Fund** means the fund established pursuant to the Inspira Settlement Agreement approved by the Bankruptcy Court.
- 8. **Insight Settlement Fund** means the fund established pursuant to the Insight Settlement Agreement approved by the Bankruptcy Court.
- 9. **MDL Court** means the United States District Court for the District of Massachusetts (at Boston) presiding over the matter entitled *In re: New England Compounding Pharmacy, Inc. Product Liability Litigation*, MDL Docket No. 2419, Master File No. 1:13-MD-2419.

- 10. **Medical Lienholder** means any insurance entity which has a statutory right to recovery of medical payments made on behalf of a Claimant, which resulted from personal injuries arising from the administration of NECC products, or which has asserted a valid lien for recovery of medical payments made on behalf of a Claimant which resulted from personal injuries arising from the administration of NECC products. Anti-Subrogation state laws in Arizona, Connecticut, Kansas, Missouri, North Carolina, New Jersey, New York and Virginia apply in making this determination.
- 11. **Medicare-Entitled Claimant(s)** means a Claimant who was eligible to receive Medicare benefits anytime between September 1, 2012 and May 31, 2013.
- 12. **MPS Class Counsel** means Marc Lipton, Rob Sickels and Marc Newman, courtappointed class counsel for the MPS Settlement. "MPS" derives from Michigan Pain Specialists.
- 13. **MPS Court** means the Circuit Court for the County of Livingston, State of Michigan presiding over *Adair et. al v. Michigan Pain Specialists, PLLC et. al*, Case No. 14-28156-NO.
- 14. **MPS Defendants** means Michigan Pain Specialists, LLC; John William Chatas; Edward Peter Washabough III, MD; Alexander George Shaloub, MD; Louis David Borjab, MD; and their insurers, Cincinnati Insurance Company and Star Insurance Company.
- 15. **MPS Settlement Fund** means the fund established pursuant to the MPS Settlement Agreement approved by the MPS Court.
- 16. **MPS Settlement Fund Administrator** means Class Action Administration LLC, 6521 West 91st Avenue, Westminster, CO 80031.
- 17. **NECC** means the New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center.
- 18. **NECC National Settlement** means the settlements with NECC, Barry Cadden, Lisa Conigliaro Cadden, Carla Conigliaro, Gregory Conigliaro, Ameridose LLC, GDC Properties Management, ARL BioPharm, Inc., Victory Mechanical Services, Inc., Liberty Industries, Inc., and their insurers., which was approved by the Bankruptcy Court in its Findings of Fact, Conclusions of Law and Order Confirming the Third Amended Joint Chapter 11 Plan of New England Compounding Pharmacy, Inc., dated May 20, 2015.
- 19. **NECC National Settlement Administrator** means Epiq Systems, Inc., 10300 SW Allen Boulevard, Beaverton, OH 97005.

- 20. **NECC Tort Trustee** means Lynne Riley, court appointed trustee under the Third Amended Joint Chapter 11 Plan of New England Compounding Pharmacy, Inc.
- 21. **Non-Participating Lienholders** means any Medical Lien Holder who is not a Participating Lien Holder.
- 22. Other Settling Defendants means NECC, Barry Cadden, Lisa Conigliaro Cadden, Carla Conigliaro, Gregory Conigliaro, Ameridose LLC, GDC Properties Management, ARL BioPharm, Inc., Victory Mechanical Services, Inc., Liberty Industries, Inc., High Point Surgery Center, Inspira Health Network, Inc., Insight Health Corporation, Michigan Pain Specialty, LLC, other parties that settle claims for injuries associated with NECC products, and their affiliates and insurers, under the Five NECCSettlements.
- 23. Participating Lienholders means the Medical Lienholders listed on Attachment F.
- 24. **Primary Lien** means a lien arising out of coverage pursuant to a GHP, Part C Medicare Plan, or workers compensation plan. Primary Lien does not include a claim by Medicaid for medical services or expenses or a claim by a Medi-Gap or Part D Medicare Plan, the Veteran's Administration, or Tricare.
- 25. **Settlement Payment or Payments** means each payment made to a Claimant from any of the Five NECC Settlements, including but not limited to any and all initial payments, final payments, or otherwise. For Claimants represented by an attorney, Settlement Payments are the gross amounts awarded before deduction for attorney fees and case expenses.